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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-----------------|-------------------------|-----------------------|------------------|
| 09/519,246 | 03/06/2000 | Stuart K. Williams | 9896.143 | 8260 |
| 7. | 590 06/27/2005 | | EXAM | INER |
| INTELLECT | UAL PROPERTY GR | GROUP BARRETT, THOMAS C | | |
| FREDRIKSON | & BYRON, P.A. | | | |
| 200 SOUTH 67 | TH STREET | | ART UNIT PAPER NUMBER | |
| SLUTE 4000 | | | 1738 | • |

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | SP |
|---|--|--|------------|
| | Application No. | Applicant(s) | |
| | 09/519,246 | WILLIAMS ET AL. | |
| Office Action Summary | Examiner | Art Unit | |
| | Thomas C. Barrett | 3738 | |
| The MAILING DATE of this communication appeariod for Reply | opears on the cover sheet w | ith the correspondence addres | ss |
| A SHORTENED STATUTORY PERIOD FOR REP THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a re - If NO period for reply is specified above, the maximum statutory perio- - Failure to reply within the set or extended period for reply will, by statu- Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b). | I. 1.136(a). In no event, however, may a sply within the statutory minimum of thin d will apply and will expire SIX (6) MON tre, cause the application to become Al | reply be timely filed rly (30) days will be considered timely. NTHS from the mailing date of this commu BANDONED (35 U.S.C. § 133). | unication. |
| Status | | • | |
| 1) Responsive to communication(s) filed on 14 | April 2005. | | • |
| 2a) ☐ This action is FINAL. 2b) ☑ Th | is action is non-final. | | |
| 3) Since this application is in condition for allow | ance except for formal mat | ters, prosecution as to the me | erits is |
| closed in accordance with the practice under | Ex parte Quayle, 1935 C.E |). 11, 453 O.G. 213. | |
| Disposition of Claims | | | |
| 4) Claim(s) <u>1,3,6,7,10,11,13,16,17 and 21-43</u> is | /are pending in the applica | lion. | |
| 4a) Of the above claim(s) is/are withdr | awn from consideration. | | |
| 5) Claim(s) is/are allowed. | | | |
| 6)⊠ Claim(s) <u>1,3,6,7,10,11,13,16,17 and 21-43</u> is | /are rejected. | | |
| 7) Claim(s) is/are objected to. | | | |
| 8) Claim(s) are subject to restriction and | or election requirement. | | |
| Application Papers | • | | |
| 9) The specification is objected to by the Examir | ner. | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ ac | cepted or b) objected to | by the Examiner. | |
| Applicant may not request that any objection to th | e drawing(s) be held in abeya | nce. See 37 CFR 1.85(a). | |
| Replacement drawing sheet(s) including the corre | ction is required if the drawing | y(s) is objected to. See 37 CFR 1 | .121(d). |
| 11) The oath or declaration is objected to by the E | Examiner. Note the attache | d Office Action or form PTO-1 | 152. |
| Priority under 35 U.S.C. § 119 | | | |
| 12) Acknowledgment is made of a claim for foreig | n priority under 35 U.S.C. | § 119(a)-(d) or (f). | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | |
| 1. Certified copies of the priority docume | nts have been received. | | |
| 2. Certified copies of the priority document | nts have been received in A | Application No | |
| Copies of the certified copies of the pri | onty documents have been | received in this National Sta- | ge |
| application from the International Bure | au (PCT Rule 17.2(a)). | | |
| * See the attached detailed Office action for a lis | st of the certified copies not | received. | • |
| | | | |
| Attachment(s) | " – | | |
| Notice of References Cited (PTO-892) | | Summary (PTO-413) (s)/Mail Date | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/06 Paper No(s)/Mail Date | | Informal Patent Application (PTO-152 | 2) |

DETAILED ACTION

REQUEST FOR CONTINUED EXAMINATION

The request filed on April 14, 2005 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/519,246 is acceptable and a RCE has been established. An action on the RCE follows.

Response to Arguments

Applicant's arguments with respect to claims 1, 3, 6-7, 10-11, 13, 16-17 and 21-43 have been considered but are most in view of the new ground(s) of rejection.

Contrary to the Applicants arguments, thin is not defined in the specification as "one to three monolayers." The specification only discloses "one to three monolayers" as an example of "thin", not as a definition.

The Applicant argues, "Applicants' reference to Clapper and seven other patents as examples of approaches to covalently attach coating agents by photochemical means does not mean that the claimed thin, conformal coatings are disclosed or inherent in the disclosure of Clapper or any of the other references. Applicants' statement is not an admission that these eight patents disclose the claimed thin and conformal coatings, inherently or otherwise. The Examiner must find actual or inherent disclosure within Clapper of this limitation related to the thin and conformal coatings." The prior office action stated "The method of coating is the same in Clapper as in the present invention as admitted by the Applicant (page 17, lines 16-22 of the specification) and therefore inherently has the same properties claimed." The PTO can

require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. When the rejection is based on 'inherency' under 35 102(b) the burden of proof is the same, which is similar to that required with respect to product-by-process claims. The inherent disclosure is admitted by the present specification. The present specification discloses, "In evaluating and comparing uncoated (or unsuitably) coated grafts with those coated in the manner presently described, it can be seen that detectable endoleaking will occur in substantially none (< 5%) of coated grafts when evaluated one-half hour after placement (the initial angiogram)." The manner(s) "presently described" include the Clapper and Guire methods. The present application cites the method disclosed by Clapper as "particularly preferred" so therefor inherently has the same properties claimed, i.e. thickness and conformal coating wherein the bioactive agent has been carefully attached (e.g., to the individual fibers making up the material, without plugging the pores therein) in a manner that provides an optimal combination of low bulk and effective thrombogenic effect in vivo. If additional steps are required for creating the "thin and conformal" coatings than a rejection based on a lack of enablement may be made because no other steps are disclosed.

In response to applicant's argument that there is no suggestion to combine the references, the examiner points out that motivation was provided in the prior office action and that the motivation itself comes directly from the cited prior art. The Applicant's arguments directed towards the combination making an inferior product. A product that is less optimal does not constitute a teaching away. In addition, the

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Applicant's arguments do not constitute evidence, e.g. the stent "would hinder the pliability of the graft"...

The Applicant also states "The dependent claims in the application contain additional limitations and combinations of limitations not disclosed in the cited references. Rejections of the independent claims do not necessarily address the limitations and combinations of limitations of the dependent claims." The Applicant fails to argue which "additional limitations and combinations of limitations not disclosed in the cited references". Any rejections of independent or dependent claims not specifically traversed in the arguments are considered final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made:

Claims 1, 3, 6-7, 10-11, 13 and 16-17 and 21-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guire (4,979,959) in view of Marin et al. (5,443,477). Guire discloses a vascular graft (col. 1, lines 31-32) with a hemostatic (thrombogenic) agent such as collagen (col. 4, lines 28-45) covalently bonded to its surface by the activation of photoreactive groups (col. 2, lines 38-46), wherein the surface can be ePTFE (Example 1) however Guire fails to disclose the vascular graft as part of an endovascular stent-graft. Marin et al. teaches an intraluminal stent that can be

reliably and readily affixed to any graft material (col. 2, lines 9-19) thus making an endovascular graft, which permits fixation of the graft to an arterial wall without sewing (col. 1, lines 66-67). It would have been obvious to one of ordinary skill in the art to combine the teaching of an intraluminal stent affixed to a graft material, as taught by Marin et al., to a vascular graft as per Guire, in order to permit fixation of the graft to an arterial wall without sewing. Please Note: The method of coating is the same in Guire as in the present invention as admitted by the Applicant (page 17, lines 16-22 of the specification) and therefore inherently has the same properties claimed. Guire also fails to specifically disclose the hemostatic collagen as type I collagen. It is well known to one of ordinary skill in the art that Type I collagen is hemostatic. See, for example, Clapper (5,744,515) column 4, lines 58-60. Therefore it would be obvious to one of ordinary skill in the art to use Type I collagen as the "thrombogenic" agent of Guire.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thomas Barrett

Examiner

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